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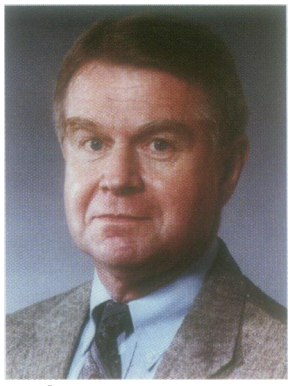
Responding to Environmental Issues: Lessons Learned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Committing resources to one project often means another issue will go unattended. The potential impact on human health and environmental quality can be significant. Admittedly, research career goals provide a subtle but distinctive driving force in priority setting and allocation of resources. Careers are affected by the nature of the scientific issues addressed: association with a highly visible problem is often more career enhancing than association with a less noteworthy issue. Thus, the response of the scientific community to emerging issues has a tremendous influence on the allocation of resources and the availability and capability of our workforce for future issues.

We, as a scientific community, should responsibly address new scientific issues by zeroing in on the highest priority needs with strategies that are in proportion to the size of the problems. Some examples may be illustrative.

Our response to the endocrine-disruptor (ED) issue is a case in point. Signals of adverse effects on wildlife species began to appear in the published literature in the 1970s (*1–7*). Effects in humans claimed to be associated with EDs in the environment were reported more recently (*8–16*). Attention to EDs hit the national radar screen with the passage of two laws: the Food Quality Protection Act in 1996 and the 1996 amendments to the Safe Drinking Water Act. Enormous amounts of human and laboratory resources were plowed into developing agreement on test batteries to detect hormonal activities of chemicals through the U.S. Environmental Protection Agency Endocrine Disruptor Screening and Testing Advisory Committee. Determining whether there were, in fact, adverse effects in humans from exposure to EDs in the environment and, if so, characterizing the scope of the problem, seemed a much lower priority. While there is general agreement that EDs cause certain adverse effects in wildlife species (*8*), there is no such consensus about adverse effects in humans. As the issue gained momentum, many scientists who were active in ED-related research segregated into camps that focused on discrediting the results of other researchers (*17*). Time and resources could have been better spent building a database for use in evaluating the conditions under which chemicals with weak hormonal activity might cause adverse effects in wildlife, domestic animals, and humans. After several years and many millions of dollars spent on research, conferences, and meetings, we still do not have validated test methods for detection of endocrine-disruptor activity. We do not know if there is a causal relationship between adverse health effects in humans and exposure to EDs in our environment. It seems obvious that our focus should be on determining whether such a relationship exists and, if so, characterizing the extent of the problem. Right now, we do not have the definitive information needed to do that.

Could we have better framed the issue and avoided the passage of laws that drove a process perhaps magnitudes larger than the problem warranted? Could we have developed a research strategy that was more constructive and less defensive? As we continue to debate whether endocrine-disrupting chemicals are a real threat to human health, the public is presented with confusion rather than resolution. Situations like this erode the public's confidence in our interest and ability to solve problems that, in their minds, came from the science community in the first place.

The ED issue is but one example of a scientific strategy with mixed agendas. There are other science-based issues from the recent past that appear to be driven by debatable agendas or mandates, for example, the controversy over the use of recombinant bovine somatotropin, the continued emphasis on TCDD many years after the sources and risks of exposure were understood, the minimal response to the threat of "mad cow disease," and the failure to use mechanistic data to regulate environmental chemicals such as chloroform. Our responses to these issues have raised questions in the minds of some of our colleagues about priorities of science, communication with the public, and the relationship between research results and regulatory decisions.

There is increasing effort today among the federal laboratories to coordinate research directions and encourage collaboration rather than competition. Congressional appropriations targeted for specific research areas encourage more cooperation between federal agencies but restrict freedom to anticipate new problems. We need to fight the fires of the day, but still be proactive in identifying those issues that truly warrant the level of attention we have given to EDs. Rather than waiting for a public outcry to drive legislative activity, experts from federal laboratories could provide background information and perspective to members of Congress about the need (or lack thereof) for legislation related to new environmental and human health issues. Antimicrobial resistance is a problem that requires such a strategy now. A recent General Accounting Office report summarizes the background and current status of this issue (*18*). There is no shortage of controversy about antimicrobial resistance, and opinions about the size of the problem range from "no concern" to "major medical disaster."

As we devise strategies to resolve problems that are in the early stages of evaluation, such as the impact of antimicrobial resistance, we should heed the lessons learned from our response to the endocrine-disruptor issue and maintain a balanced approach that will maximize our efficiency and effectiveness in the future.

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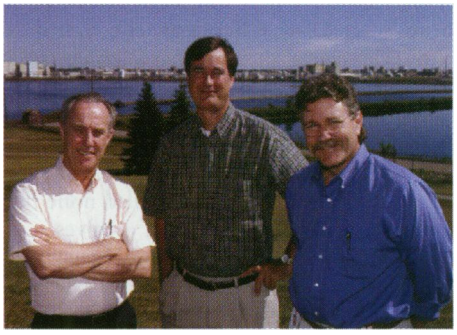
Toxicology: Judge Data or Dollars?

Research should be judged on the basis of scientific merit, without regard for funding source or where the studies are conducted...

[Society of Toxicology. SOT Principles for Research Priorities in Toxicology. Available: http://www.toxicology.org/AboutSOT/about.html (1999).]



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The knowledge gained by our work as toxicologic scientists ranges from molecular mechanisms to clinical signs of toxicity, from physiologically based pharmacokinetics to tumor counts. Any of this research, from any source, may be translated into regulatory action in order to protect the public and the environment; thus, society is best served by the best science from every source. The challenge is to find the criteria to accurately and, increasingly, quickly judge which studies are valid and appropriate to affect regulation. Cynics make these quick judgments based on funding sources; traditionalists trust the proven, but slow, peer-review process; regulatory agencies want to see raw data from industry, but have implicitly trusted and exempted academia from this scrutiny. Needs for confidentiality place limits on disclosure, but they do not preclude a more even and open approach to data from all sources. Greater disclosure will result in a scientific process that is faster, better, and more trustworthy—"trust" is the key word here. But, as a former U.S. president said near the end of the Cold War, "Trust but verify."

Verification was the apparent goal of a few lines buried deep in the voluminous 1999 Omnibus Spending Bill (*1*). It states

> That the Director of OMB amends section _.36 of OMB Circular A-110 to require Federal awarding agencies to ensure that all data produced under an award will be made available to the public through the procedures established under the Freedom of Information Act.

This new law has provoked, according to one editorial, "...howls of protest from scientists, their institutions, and the federal agencies that fund scientific research" (*2*). However, major scientific societies, including the American Chemical Society, the Council for Chemical Research, and the American Association for the Advancement of Science, all support, in principle, the need to assess the validity of such research results (*3*). Recently, it has again been made clear that the issues of quality and reliability of toxicology data and its reasoned interpretation for regulatory purposes are critical (*4*); the question is how best to accomplish that end.

The tried and true way, the unfettered peer-review process, is and will continue to be the keystone of scientific progress. However, it rarely depends on the scrutiny of raw data; rather, the peer-review process ultimately depends on the independent replication of important findings. Thus, it is slow, sometimes painfully so. Democracy is a similarly empirical endeavor. Like science, the process is generally ponderous and tentative, and our laws are often badly out of synchronization with science, a condition regularly exacerbated by swells of public concern. Fueled by a willing press, the public perception of a crisis can rapidly propel new regulations that may never gain a scientific foundation, nor are they repealed when science catches up. Rational or not, an alarmed public, or more often issue advocacy groups, call for immediate action well before any reasoned assessment of what action, if any, is called for. The scientific community is left unprepared. Poor decisions follow, which may have unintended consequences, levy unnecessary expense on taxpayers, and provide no demonstrable benefit for public health or the environment.

Unfortunately, as a preventative for bad regulation based on unvalidated or preliminary science, the new amendment to Circular A-110 is a crude vaccine that will cause more problems than it could possibly cure. The apparent intent of the law is laudable, but its shortcomings are serious: It lacks adequate protection for intellectual property, patient privacy, and against legal abuse by those who might be tempted to harass researchers with unreasonable